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June 20, 2024

Via CM/ECF only

Hon. Georgette Castner, U.S.D.J.
United States District Court, District of New Jersey
402 East State Street
Trenton, NJ 08608

Re: *Lovaglio v. Baston*, No. 3:23-cv-21803-GC-RLS

Dear Judge Castner:

This office represents Defendants, Kaitlan Baston, Commissioner of the New Jersey Department of Health (the “Department”), and Nancy Scotto-Rosato, Assistant Commissioner for the Division of Family Health Services (collectively, the “State”), in the above-referenced matter. In accordance with the Court’s judicial preferences, we write to request a pre-motion conference prior to filing a 12(b)(1) motion to dismiss. Such a conference is especially warranted here in light of recently announced changes to the public-health program at the center of this lawsuit.

This matter concerns the State’s Newborn Screening Program (the “Program”), which, like similar programs in all 50 States, serves to protect the health and quality of life of infants born in New Jersey by screening a small sample of their blood (five “bloodspots”) for 61 disorders soon after birth. Under the retention policy challenged in this litigation (the “Policy”), the Program has retained bloodspots for 23 years, but parents and legal guardians may obtain destruction of bloodspots linked to their children.

Plaintiffs in this putative class action are three children and their parents, who argue that the Program’s pre-existing Policy (though not the initial screening,



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Compl. ¶¶ 19, 124) violates the children’s Fourth Amendment rights to be free from unreasonable seizures (Count I) and the parents’ due process rights to direct the care, custody, and control of their children (Count II). Plaintiffs seek declaratory and injunctive relief. Compl. ¶¶ 35-36.

As this Court is aware, Plaintiffs and the State previously engaged in extensive settlement discussions, but were unable to reach a mutually agreeable resolution. As of today, June 20, the State has nevertheless announced (and begun taking steps to implement) significant changes to the Policy that bear on this litigation, as detailed in the attached Notice. Most relevantly, under the new Policy, the Department will retain bloodspots that tested negative for only two years, unless a parent or legal guardian expressly requests a longer retention period (up to 10 years). If no such request is received, the Department will queue the bloodspots up for destruction at the two-year mark. (Positive bloodspots will be subject to a slightly different, though also revised, regime.) As before, parents and legal guardians may obtain destruction of bloodspots linked to their child (an option Plaintiffs have declined to exercise).

In addition, the New Jersey Attorney General has today issued a new, binding Law Enforcement Directive, which is also attached hereto. Under that Directive, law enforcement entities in New Jersey that wish to access information from the Program must obtain approval from the Director of the Division of Criminal Justice. Approval will be granted only where law enforcement seeks (1) a special type of court-issued subpoena, akin to a warrant (not a grand jury subpoena); (2) a warrant; or (3) in tragic cases in which law enforcement is seeking simply to identify a missing or deceased child, an administrative subpoena authorized under N.J. Stat. Ann. § 52:17B-9.7 to -9.8d (or other appropriate court process contemplated by that statute).

In light of these changes, the State anticipates moving to dismiss Plaintiffs’ operative complaint. The State would not, however, object to Plaintiffs voluntarily amending their complaint, assuming they wish to challenge the new Policy. *See, e.g., Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 111 (2d Cir. 2016) (explaining that plaintiff was “free to challenge” new standards, but “must do so through an amended complaint”).

First, the Parent-Plaintiffs lack Article III standing for their due process claim. The Policy does not interfere with the Parent-Plaintiffs’ ability “to make decisions concerning the care, custody, and control of their children.” *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (plurality op.). Nothing about the Policy affects the Parent-

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Plaintiffs’ decision-making about their children’s care (indeed, it also permits them to obtain destruction); it merely provides information. Because the Policy does not mandate use of that information in any way, *see* N.J. Stat. Ann. § 26:2-111, Parent-Plaintiffs cannot establish Article III standing on Count II.

Second, given the new Policy, Plaintiffs’ Complaint is moot. Mootness doctrine ensures that federal-court disputes remain “embedded in an[] actual controversy about the ... particular legal rights” the plaintiffs seek to vindicate. *Clark v. Governor of New Jersey*, 53 F.4th 769, 775 (3d Cir. 2022), *cert. denied sub nom. Clark v. Murphy*, 143 S. Ct. 2436 (2023). Here, where Plaintiffs’ current Complaint seeks declaratory and injunctive relief as to a Policy that is now in the process of being substantially changed, their Complaint no longer implicates an actual controversy, and thus relief “would serve no purpose.” *Khodara Env’t, Inc. ex rel. Eagle Env’t L.P. v. Beckman*, 237 F.3d 186, 194 (3d Cir. 2001). Nor can the State “reasonably be expected to engage in the challenged behavior again” under these circumstances, *see Hartnett v. Pa. State Educ. Ass’n*, 963 F.3d 301, 306 (3d Cir. 2020)—least of all with respect to the bloodspots linked to these Child-Plaintiffs who (per their Complaint) tested negative and are now more than two years old, *see* Compl. ¶¶ 66, 74-75. Assuming Plaintiffs do not request continued retention, those bloodspots will soon be irrevocably destroyed under the new Policy.

Finally, to the extent Plaintiffs wish to wait for the State to fully implement the new Policy, the State would urge the Court in the alternative simply to hold the matter in abeyance. In any event, these circumstances strongly warrant a pre-motion conference, given the parties’ and the Court’s joint interests in an efficient means of litigating any challenge Plaintiffs wish to bring to the new Policy.

Respectfully submitted,

MATTHEW J. PLATKIN
ATTORNEY GENERAL OF NEW JERSEY

By: /s/ Michael R. Sarno
Michael R. Sarno
Deputy Attorney General (NJ Bar #028492004)

cc: All counsel of record (via CM/ECF)



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KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

**PUBLIC NOTICE OF
CHANGE TO NEWBORN SCREENING PROGRAM'S RETENTION POLICY**

June 20, 2024

As in all States, each baby born in New Jersey must be screened for certain disorders that can cause serious health problems. New Jersey law requires that babies born in our State be tested for 61 disorders within 48 hours of birth, a process that starts with a "heel prick" blood draw that generates five spots of blood, or "bloodspots," that can be used as test samples. The Department's lab then conducts tests and shares the results with the baby's doctor.

This notice describes changes to the Department's policy for retaining newborn screening bloodspots. Currently, the Department retains bloodspots for 23 years. **Under the new policy, the Department will retain identified bloodspots for only two years, unless a parent or legal guardian expressly requests a shorter or longer retention period as described below.** The Department has begun taking steps to implement the new policy, though destruction of existing samples will not begin until November 1, 2024, and will take some time. Under the new policy:

- The Department will use retained bloodspots only for the following purposes: (1) newborn screening for a child; (2) routine laboratory quality assurance and quality control; and (3) the development of new tests for disorders. Any bloodspots used for the second or third purposes will be de-identified prior to that use.
- Any retained bloodspots will not be released to any other third-party in **identified** form (*i.e.*, with identifying information about the child), without the consent of a parent or legal guardian.
- Any retained bloodspots will not be released to any other third-party in **de-identified** form (*i.e.*, without any identifying information about the child), unless consistent with federal statutes and regulations.
- Parents and legal guardians who want the Department to **retain** bloodspots linked to their child for more than two years may request that the Department do so (for up to ten years) by submitting the Extended Retention Form, available [here](#). The Department will be conducting outreach regarding the new policy to doctors and other stakeholders involved in caring for children who tested positive for one or more of the conditions on the newborn screening panel.
- Parents and legal guardians who want the Department to **destroy** all bloodspots linked to their child may, at any time after the initial screening (including before their child is two

years old), direct the Department to do so by submitting a Destruction Form, available [here](#).

- For bloodspots that tested negative, unless a parent or legal guardian has directed otherwise, the Department will queue the bloodspots for destruction at the two-year mark.
- For bloodspots that tested positive for any of the 61 conditions:
 - The Department will de-identify one bloodspot and retain that de-identified bloodspot no longer than 10 years, using it for routine laboratory quality assurance, quality control, and the development of new tests for disorders.
 - The remaining four bloodspots will be queued for destruction at the two-year mark, as with bloodspots that tested negative.
- Bloodspots never have been and **never will be sold** to any person or entity.
- The New Jersey Attorney General has recently issued a binding Law Enforcement Directive that limits the circumstances under which state and local law enforcement may seek to obtain information from the newborn screening program, available [here](#). The Department will not release such information to law enforcement without the consent of a parent or legal guardian, except as consistent with the Attorney General's Directive.



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Director

ATTORNEY GENERAL LAW ENFORCEMENT DIRECTIVE NO. 2024-03

TO: All Law Enforcement Chief Executives and County Prosecutors

FROM: Matthew J. Platkin, Attorney General

DATE: June 20, 2024

**SUBJECT: Investigatory Use of Documentary Records and Physical Blood Samples
Maintained by the Newborn Screening Program**

I. Introduction and Overview

The Newborn Screening Program is an important public-health program designed to detect unseen illnesses and connect newborn infants with comprehensive healthcare and services. See N.J.S.A. 26:2-110, -111; N.J.A.C. 8:18-1.12. New Jersey law requires that every baby born in the State must have a bloodspot screen taken within 48 hours of birth to test for various conditions that can cause serious health problems or even death, unless a parent or guardian objects on religious grounds. See N.J.S.A. 26:2-110, -111; N.J.A.C. 8:18-1.12. The Program is critical to helping medical professionals, parents, and guardians quickly detect a variety of congenital disorders, and to helping prevent future problems related to those conditions through early diagnosis and treatment. It also provides universal access to screening for all babies, including those who otherwise might not have sufficient access to care. See N.J.S.A. 26:2-110.

Crucial to the success of the Program is that information gathered through it is kept private. N.J.S.A. 26:2-111; N.J.A.C. 8:18-1.13. And given the sensitivity inherent in this Program, law enforcement has almost never sought to use this material as part of an investigation—indeed, the Department of Health in 2022 revealed that only five grand jury subpoenas had been received (from four law enforcement agencies) over the preceding five years, an average of one per year. But even the infrequent use of information gathered via a public-health program can impact the public's trust in such programs, which can in turn jeopardize public safety and public health. Therefore, in the interests of bolstering public confidence in this medical-screening program, this Directive adds new and important limits to ensure that law enforcement agencies will only seek such information in genuinely exceptional circumstances. It does this by imposing new approval requirements for the rare cases in which law enforcement seeks to obtain newborn "bloodspot" information, and designates the legal process this Office will require all law enforcement agencies to follow going forward.

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Therefore, pursuant to the authority granted to me under the New Jersey Constitution and the Criminal Justice Act of 1970, N.J.S.A. 52:17B-97 to -117, which provides for the general supervision of criminal justice by the Attorney General as chief law-enforcement officer of the State in order to secure the benefits of a uniform and efficient enforcement of the criminal law and the administration of criminal justice throughout the State, I hereby direct all law enforcement and prosecuting agencies operating under the authority of the laws of the State of New Jersey to implement and comply with the directives outlined below:

II. Process and Approval Requirements

A. Requirements

Before seeking release of documentary records or physical bloodspots maintained by the Newborn Screening Program, a law enforcement agency shall first seek approval from the Director of the Division of Criminal Justice. Requests for approval must be made in writing and must explain why this is an exceptional circumstance that necessitates seeking information from the Program and why less intrusive means will not suffice. In keeping with past practice, a request for such information regarding an individual who is not the victim in the case should be exceedingly rare.

B. Appropriate Legal Process

To bolster public confidence in the newborn screening program, any documentary records and/or physical bloodspots maintained by the Newborn Screening Program shall be obtained only by one of the following forms of appropriate legal process based on the facts presented:

1. a court-issued Dyal subpoena rather than grand-jury subpoena, see State v. Dyal, 97 N.J. 229, 232 (1984) (“[T]o obtain the results of a blood test protected by the patient-physician privilege, the police should apply to a municipal court judge for a subpoena duces tecum.”), abrogated on other grounds by State v. Adkins, 221 N.J. 300, 316 (2015); or
2. a search warrant based on probable cause, see U.S. Const. amend. IV.; N.J.S.A. Const. art. 1, ¶ 7; or
3. an administrative subpoena (or appropriate court process) issued in a missing-persons or unidentified-body case under N.J.S.A. 52:17B-9.7 to -9.8d.

III. Other Provisions

A. Non-enforceability by third parties. This Directive is issued pursuant to the Attorney General’s authority to ensure the uniform and efficient enforcement of the laws and administration of criminal justice throughout the State. Nothing in this Directive shall be construed in any way to create any substantive right that may be enforced by any third party.

B. Severability. The provisions of this Directive shall be severable. If any phrase, clause, sentence, or provision of this Directive is declared by a court of competent

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jurisdiction to be invalid, the validity of the remainder of the Directive shall not be affected.

- C. Questions.** Any questions concerning the interpretation or implementation of this Directive shall be addressed to the Director of the Division of Criminal Justice, or their designee.
- D. Effective date.** This Directive shall take effect immediately, and shall remain in force and effect unless and until it is repealed, amended, or superseded by Order of the Attorney General. All law-enforcement agencies are encouraged to take any action they deem necessary related to training on this Directive.



Matthew J. Platkin
Attorney General

ATTEST:



Lyndsay V. Ruotolo
First Assistant Attorney General

Dated: June 20, 2024